



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0473-30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, Sherrette.Funn@hhs.gov or (202) 264-0041, or PRA@HHS.GOV. When submitting comments or requesting information, please include the document identifier 0990-0473-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HHS Subpart C Certification Form

Type of Collection: Revision

Abstract: The Office for Human Research Protections (OHRP) is requesting a three-year extension of OMB No. 0990-0473, the HHS Subpart C Certification Form. The purpose of this form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to obtain authorization to include prisoners in HHS-conducted or supported human subjects research. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time.

Type of Respondent: Institutions or Organizations operating Institutional Review Boards (IRBs) that have enrolled or are planning to enroll prisoners in human subjects research conducted or supported by HHS.

Estimated Annualized Burden Table

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Institutions or Organizations operating IRBs	25	2	1.0	50
Institutions or Organizations operating IRBs	5	3	1.0	15
Total				65

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.